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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,379	03/22/2001	Mary Gerritsen	09800081-0026	3936

23552 7590 08/23/2005

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,379

Applicant(s)

GERRITSEN ET AL.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,47-50 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,47-50 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/20/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/9/2005 has been entered.
2. Claims 2,5-46, and 51 are canceled without prejudice or disclaimer.
3. Claims 1,3-4,47-50, and 52-54 are pending and examined on the merits.

Information Disclosure Statement

4. The Information Disclosure Statement filed 6/9/2005 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections Maintained - 35 USC § 101 &

35 USC § 112, 1st paragraph

5. The rejection of claims 1,3,4,47-50, and 52-54 under 35 USC § 101 as lacking an substantial and well established utility is maintained for the reasons of record. Applicant argues that the instantly claimed invention has a substantial, a well established utility and meets the criteria for utility. Specifically, applicant argues that the claimed polypeptide has a specific and substantial utility as a marker for angiogenesis and

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therefore has utility as an angiogenesis marker. Moreover, applicant argues that the claimed invention is potentially useful in the treatment of tumors and cancers

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The arguments present in the arguments submitted 6/9/2005 has been previously argued. Specifically, the claims are drawn to a polypeptide while the disclosure in the specification is drawn primarily to nucleic acid molecules. Thus the up-regulation of the nucleic acid does not necessarily correlate to the protein levels and therefore the findings are not commensurate in scope to the claimed invention and therefore the utility applied to the nucleic acid cannot be readily conveyed to the claimed polypeptide in view of the general unpredictability of correlating nucleic acid expression levels and to protein expression levels.

Applicant additionally contends that the examiner must provide evidence to show that the statements of asserted utility are considered "false" by a person of skill. To support the assertions of utility, applicant contends that one of skill in the art would "more likely than not expect hBAZF polypeptide is expressed and that an increase in hBAZF mRNA correlates with an increase in hBAZF polypeptide expression" based on the rebuttal references cited (i.e. Alberts, Zlot *et al* , Horikoshi *et al* , Orntoft, and Futcher *et al*).

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejections of record. As indicated in the last office action, the cited references provided actual data that correlates mRNA expression levels to actual protein levels. In the instant case, the applicant has only provided mRNA expression levels and one of skill in the art, given the unpredictability associated with correlating

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mRNA expression and protein levels, cannot adequately extrapolate that information to the instant case. The specification fails to provide a predictable nexus between the detection of angiogenesis with the expression of the claimed polypeptide. The specification provides neither guidance on nor exemplification of how to correlate protein expression with the ability to provide a diagnostic evaluation of any disorder or prediction of angiogenic events. Thus, in the absence of any correlation between the claimed protein with any known disease or disorder, any information obtained from various protein expression profiles in both non-angiogenic and angiogenic tissue only serves as the basis for further research on the observation itself. Therefore, absent evidence of the protein's expression including the correlation to a diseased state, one of skill in the art would not be able to predictably use the protein in any diagnostic setting without undue experimentation.

Moreover, applicant must provide a substantial and specific utility for the instant invention and not rely on the general teachings of the art to support a utility of the instant invention. More specifically, applicant's assertion that the instant invention can be used as a diagnostic tool is a general utility that has not been associated with any specific disease or condition. Thus given the lack of association with a specific disease, a substantial utility has not been provided.

Finally, applicant argues that the examiner has not provided any evidence or reasoning that the instant invention would be considered "false" by the skilled artisan. Applicant's arguments have been carefully considered but are not deemed persuasive

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to overcome the rejection of record. Specifically, the credibility of the claimed invention is not at question, rather the disclosure of a specific and or substantial utility.

Therefore, the rejection of claims under 35 USC § 101 as lacking a substantial and specific well established utility is maintained for the reasons of record. In addition, claims 1,3,4,47-50, and 52-54 also remain rejected under 35 USC §112, 1st paragraph for lacking a substantial and specific utility.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

6. The rejection of claims 1,3-4,47-50, and 52-54 under 35 USC § 112, 1st paragraph as lacking adequate written description is maintained for the reasons of record. Applicant argues that the instant invention is now newly claimed by specifically reciting a functional limitation (i.e. transcriptional repressor activity). Applicant additionally contends that the specification teaches variants of BAZF (specifically points to page 74). And finally applicant argues that the skilled artisan could identify variants of BAZF based on specific domain structures (i.e. BTB/POZ and zinc fingers) and its functional activity. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Applicant's base the written description of variant language on the disclosure of a single species of the claimed polypeptide (i.e. SEQ ID No: 4). However, the claimed invention encompasses a genus of polypeptides (i.e. sequences that are at least 90% homologous to SEQ ID No: 4). The disclosure of a single species does not adequately describe nor represent the genus of sequences encompassed by the recited language

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of at least 90% identical to SEQ ID No: 4. Applicant's amendment to indicate functional language (i.e. transcriptional repressor activity) in this case does not overcome the rejection of record because little information is provided for the domain that is responsible for the transcription activity. Applicant indicates that a "middle sequence" is response for such activity, but little information (i.e. specific sequence) is provided.

Thus the rejection of claims under 35 USC 112, 1st paragraph as lacking an adequate written description is maintained for the reasons of record.

Conclusion

No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
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August 15, 2005

Sheela J. Huff
SHEELA HUFF
PRIMARY EXAMINER